Cartesian Therapeutics Announces Strong Efficacy Signal in Phase 2 Trial of Descartes-08 in Patients with SLE and Expansion of Clinical Development into Myositis

November 13, 2025

100% LLDAS response rate observed in patients with SLE who received Descartes-08 in Phase 2 open-label trial reaching Month 3 follow-up (n=3)

Disease remission reported as DORIS response seen in 2 out of 3 patients reaching Month 3 follow-up (n=3)

Descartes-08 in SLE patients was observed to have a favorable safety profile supporting outpatient administration without the need for lymphodepleting chemotherapy

Myositis seamless adaptive clinical trial design provides potential opportunity for a single pivotal trial expected to commence in 1H26

FREDERICK, Md., Nov. 13, 2025 (GLOBE NEWSWIRE) -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering cell therapy for autoimmune diseases, today announced positive initial data from the ongoing Phase 2 open-label trial of Descartes-08 in patients with systemic lupus erythematosus (SLE). Descartes-08, Cartesian's lead cell therapy candidate, is an autologous anti-B cell maturation antigen (BCMA) chimeric antigen receptor T-cell therapy (CAR-T).

"The responses observed in all participants reaching Month 3 follow-up to date in the ongoing Phase 2 SLE trial serves as strong validation for our proprietary platform technology and supports the potential of Descartes-08 to expand the reach of cell therapy for the treatment of autoimmune diseases," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Consistent with clinical data reported to date from our myasthenia gravis program, Descartes-08 was well-tolerated in the outpatient setting and we saw a 100% LLDAS response rate in the three patients who reached Month 3. With the positive data in SLE supporting the clinical effect of Descartes-08, we are now optimistic about the opportunity to initiate a Phase 2 trial in myositis. Myositis is a disease with significant unmet medical need which we believe will provide Cartesian with a streamlined clinical development pathway in a disease with a large, underserved community."

Topline Data from Phase 2 Trial of Descartes-08 in SLE

The Phase 2 open-label trial was designed to evaluate outpatient administration of Descartes-08 without preconditioning chemotherapy or integrating vectors for the treatment of patients with moderate or severe SLE refractory to immunosuppressant therapy. The primary outcome measure assesses safety and tolerability, with secondary outcome measures assessing preliminary efficacy.

- Initial data reported significant reduction in disease activity following initial Descartes-08 treatment with 100% of participants who reached Month 3 follow-up (n=3) achieving Lupus Low Disease Activity State (LLDAS) response, defined by specific criteria that indicate low disease activity, improved patient outcomes, and sustained symptom improvement[1]. These results further validate the clinical effect of Descartes-08 in the field of autoimmune disease and the Company will continue to analyze the data from SLE to determine the next steps for the program.
- Disease remission reported as DORIS response was seen in 2 out of 3 participants at Month 3. DORIS is defined as the Definition of Response in SLE indicating a clinical SLE Disease Activity Index (SLEDAI)-2K score of 0 and physician global assessment (PGA) of less than 0.5.
- Descartes-08 continues to be observed as well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy. Adverse events were transient and mostly mild, and notably, there were no cases of cytokine release syndrome (CRS), and no cases of immune effector cell-associated neurotoxicity syndrome (ICANS).
- Correlative biomarkers support application of Descartes-08 in multiple autoimmune diseases observed through a statistically significant ($p<0.01$) decrease in proinflammatory cytokines associated with SLE pathogenesis (IL7, IL10, CCL20, ST1A1). Additionally, significant decreases were observed in plasmacytoid dendritic cells (pDCs) 3 months after receiving Descartes-08 in both myasthenia gravis (MG) and SLE patients, supporting the expansion into myositis, an autoimmune indication with a known pDC correlation.

At this time, Cartesian plans to pause further development of Descartes-08 in SLE, including enrollment in the Phase 2 trial, to prioritize the opportunities in MG, currently in Phase 3, and myositis.

Myositis Expansion

With strong mechanistic alignment with existing clinical data in MG and SLE, Cartesian today announced the planned expansion of Descartes-08 into myositis, a significantly underserved market with high unmet need. The Company plans to initiate a seamless adaptive clinical trial design which provides a potential opportunity for a single pivotal trial planned to commence in the first half of 2026.

The randomized, double-blind, placebo-controlled Phase 2 trial in myositis is designed to assess Descartes-08 versus placebo (1:1 randomization) administered as six weekly outpatient infusions without preconditioning chemotherapy in up to 50 patients with moderate to severe multi-refractory dermatomyositis and antisynthetase syndrome. The primary endpoint is expected to assess safety and efficacy of Descartes-08 compared to placebo added to standard of care in patients with myositis at Week 24. An interim analysis is expected after ten patients are enrolled and reach the primary endpoint, at which point sample size assumptions will be revised to what is necessary to support a seamless pivotal trial pending FDA review based on the preliminary efficacy data available at such time. The Company plans to file an investigational new drug application (IND) for this trial by the end of 2025.

Preliminary Descartes-15 Safety Data

The Company today reported results from the Phase 1 dose escalation trial designed to assess safety and tolerability of outpatient administration of Descartes-15 in patients with multiple myeloma.

In this trial, no significant adverse events or dose-limiting toxicities were reported in any participants (n=3). The only Descartes-15-related adverse event was a grade 2 hypotension occurring after the first two infusions.

Despite favorable safety data now in hand, Cartesian plans to pause the development of Descartes-15 to prioritize opportunities for Descartes-08 in MG and myositis.

Cash Runway

Following the pause in development of both Descartes-15 in multiple myeloma and Descartes-08 in SLE, the Company expects current cash resources to support planned operations, including the completion of its ongoing Phase 3 AURORA trial for Descartes-08 in MG and initiation of its Phase 2 myositis trial, through mid-2027.

About Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an incurable chronic autoimmune disease marked by systemic inflammation that affects multiple organ systems including the skin, joints, kidneys, brain, and heart. The symptoms of SLE can range from mild to life-threatening and often include fatigue, joint pain, rash, and fever. SLE impacts approximately 1.5 million people in the United States.

About Myositis

Myositis is a rare set of pathogenic autoantibody-driven diseases characterized by inflammation and muscle weakness. Myositis symptoms can range from mild to life-threatening and symptoms often include muscle weakness, joint or muscle pain, fatigue, swelling, trouble breathing or swallowing, and arrythmia. Myositis impacts approximately 80,000 people in the United States.

About Descartes-08

Descartes-08, Cartesian's lead cell therapy candidate, is an autologous chimeric antigen receptor T-cell therapy (CAR-T) product targeting B-cell maturation antigen (BCMA) in clinical development for generalized myasthenia gravis (MG) and myositis. In contrast to conventional DNA-based CAR T-cell therapies, Cartesian's CAR-T administration is designed to not require preconditioning chemotherapy, can be administered in the outpatient setting, and does not carry the risk of genomic integration associated with cancerous transformation. Descartes-08 has been granted Orphan Drug Designation and Regenerative Medicine Advanced Therapy Designation by the U.S. Food and Drug Administration for the treatment of MG, and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.

About Descartes-15

Descartes-15 is a next-generation, autologous anti-BCMA CAR-T cell therapy. In preclinical studies, Descartes-15 has been observed to achieve an approximately ten-fold increase in CAR expression and selective target-specific killing, relative to Descartes-08. Similar to Descartes-08, Descartes-15 is designed to be administered without preconditioning chemotherapy and does not use integrating vectors.

About Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering cell therapy for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is a CAR-T in Phase 3 clinical development for patients with generalized myasthenia gravis with plans to initiate a Phase 2 trial in myositis. For more information, please visit www.cartesiantherapeutics.com or follow the Company on LinkedIn or X, formerly known as Twitter.

Forward Looking Statements

Any statements in this press release about the future expectations, plans and prospects of the Company, including without limitation, statements regarding the Company's expected cash resources and cash runway, the ability of the Company's product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company's other product candidates to treat myasthenia gravis, juvenile myasthenia gravis, systemic lupus erythematosus, juvenile systemic lupus erythematosus, juvenile dermatomyositis, anti-neutrophil cytoplasmic antibody-associated vasculitis, myositis, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, including the ongoing Phase 3 AURORA trial of Descartes-08 in myasthenia gravis, the planned Phase 2 pediatric basket trial of Descartes-08 in juvenile dermatomyositis, juvenile systemic lupus erythematosus, juvenile myasthenia gravis, and anti-neutrophil cytoplasmic antibody-associated vasculitis, the ongoing Phase 2 trial of Descartes-08 in systemic lupus erythematosus, and the planned Phase 2 trial of Descartes-08 in myositis, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, including the number of trials that may be necessary in order to obtain marketing approval, the Company's ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, political uncertainty, the Company's reliance on third parties to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts, pandemics, and macroeconomic impacts, and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this press release, except as required by law.

Investor Contact
Megan LeDuc
Associate Director of Investor Relations
megan.leduc@cartesiantx.com

Media Contact
David Rosen
Argot Partners
david.rosen@argotpartners.com

[1] A fourth patient has not yet reached Month 3 as of November 13, 2025.

Source: Cartesian Therapeutics, Inc.